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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,903	08/22/2003	Daniel M. Lieberman	3998P2652	1335
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WEISS & MOY PC 4204 NORTH BROWN AVENUE SCOTTSDALE, AZ 85251				
EXAMINER				
MOULTON, ELIZABETH ROSE				
ART UNIT		PAPER NUMBER		
3767				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/646,903

Applicant(s)

LIEBERMAN, DANIEL M.

Examiner

ELIZABETH R. MOULTON

Art Unit

3767

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 14-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 14-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The declaration under 37 CFR 1.132 filed 18 May 2009 is insufficient to overcome the rejection of claims 14-16 and 18-21 based upon Wong et al as set forth in the last Office action because: declarant has argued that the balloon of Wong prevents the device from being used in the subarachnoid space. The balloon is placed in a lateral ventricle (68, Fig 8) not in the subarachnoid space (70, Fig 8) and therefore has no impact on the drainage and irrigation of the subarachnoid space.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 14-16 and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al (US 7,004,961; see also provisional application 60/438904). Wong teaches a method of treating a subdural hematoma comprising the steps of:

Inserting a dual-lumen catheter (174, Fig 6) into a subdural space (Fig 8);
draining said subdural space (via catheter F and drainage port 184A); and irrigating said subdural space (via catheter E and irrigation port 183A). See Col 9 lines 50+: "The

device (174) may alternatively include another irrigation catheter E and another aspiration catheter F disposed within the tube 176 and communicate with connectors 183, 184 respectively. The distal end of **irrigation** catheter E exits through a side port 183A in device 174 to reside in the **subarachnoid**/subdural space(s) 70. Similarly, the distal end of **aspiration** catheter F also exits through a side port 184A in device 174 which would reside in the **subarachnoid**/subdural space(s) 70."

As to claim 18, see pressure valve 152 and 216, Fig 9. As to claim 19, see irrigation container 222, Fig 9. As to claim 20, see luer lock 218. As to claim 21, see drainage container 224.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 17 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong as applied to claims above.

Claim 17: Wong does not teach the size of his drainage perforations. Since the applicant has not stated that the size of the drainage holes solves a stated problem or serves a particular purpose, and because both the holes of Wong and the applicant's holes are designed to drain fluid from the subdural space, it would have been a matter of obvious design choice to make the holes of Wong .5 to 2 mm in diameter.

Claims 22-25: Wong does not specifically teach drilling a hole in the skull. Wong shows his catheter inserted into the skull 72 through "surgical opening" 62. Fig 4. One of ordinary skill in the art would recognize that drilling is a common way to open a hole in a bone, especially the skull, and would have expected drilling to produce a surgical opening in the skull. As to claim 23, see needle 12. As to claim 24, the use of a guide wire in placement of surgical devices in the body is well known in the art. As to claim 25, see stylette 14.

5. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong as applied to claims above, and further in view of DARDIK et al (Journal of Vascular Surgery).

Wong teaches the limitations of the dual lumen catheter as above, but is silent on the duration of irrigation and drainage of the subdural hematoma.

Dardik et al teach that drains are removed from patients after three days (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the dual lumen catheter for three days, as taught by Dardik et al, as a well known medical procedure.

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong as applied to claims above, and further in view of Lamard et al (US 6,899,726).

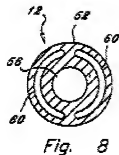
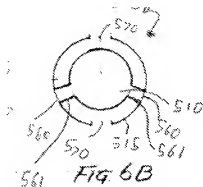
Wong does not teach the configuration of the drainage channel and irrigation channel as claimed. Wong shows the channels as being parallel in the catheter. Lamard teaches a dual lumen catheter (Fig 6-8) with a drainage channel (60) and an irrigation channel (56) inside the drainage channel comprising a plurality of tubes (each side of channel

56) and coupled to the drainage channel (via 52, Fig 8) to support the irrigation channel. Larnard teaches that the configuration of Fig 8 is easily substituted for the configuration of Fig 6, which is the same configuration taught by Wong. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the lumen arrangement shown in Fig 8 of Larnard as a simple substitution for the arrangement of Wong as they are known equivalents in the art.

Response to Arguments

Applicant's arguments filed 18 May 2009 have been fully considered but they are not persuasive. Regarding Wong, Applicant argues Wong does not expressly disclose draining and irrigating the subarachnoid space. See previously cited portion of Wong at Col 9 lines 50+: The device (174) may alternatively include another **irrigation catheter E** and another **aspiration catheter F** disposed within the tube 176 and communicate with connectors 183, 184 respectively. The **distal end of irrigation catheter E** exits through a side port 183A in device 174 to reside in the **subarachnoid/subdural space(s) 70**. Similarly, the **distal end of aspiration catheter F** also exits through a side port 184A in device 174 which would reside in the **subarachnoid/subdural space(s) 70**. Wong does expressly disclose irrigation and aspiration (drainage) of the subdural space as claimed. Aspiration and drainage are the same thing.

As to Wong and Lanard, compare Fig 8 of Lanard with Fig 6B of applicant, which purportedly shows the irrigation tubes supporting the drainage tube. The rejection is maintained.



Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ELIZABETH R. MOULTON** whose telephone number is (571)272-9970. The examiner can normally be reached on 7:00-3:30 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELIZABETH R MOULTON/
Examiner, Art Unit 3767
/Kevin C. Simons/

Supervisory Patent Examiner, Art Unit 3767